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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/711,272      | 11/09/2000  | Timothy Norris       | 62814-A/JPW/GJG     | 6700             |

7590

04/25/2003

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EXAMINER

MCKENZIE, THOMAS C

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 04/25/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/711,272

Applicant(s)

NORRIS ET AL.

Examiner

Thomas McKenzie Ph.D.

Art Unit

1624

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 February 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 05 March 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_


3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 1,5,24-32,50,52-54,61 and 64-91.Claim(s) objected to: 2-4,6,7,15,16,23,58-60 and 62.Claim(s) rejected: 14,17-22 and 63.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

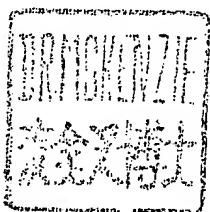
8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5.
10. ☐ Other: \_\_\_\_\_

  
MUKUND J. SHAH  
SUPERVISORY PATENT EXAMINER  
GROUP 1700

Continuation of 3. Applicant's reply has overcome the following rejection(s): Applicants cancellation of claims 55-57 renders moot the objection made in point #6 of the final rejection. Applicants' deletion of "prophylaxis" from claim 50 overcomes the enablement rejection made in point #10. Applicants' amendment to claim 63, specification they intent to treat tumors overcomes the indefiniteness rejection made in point #11. Applicants' amendments to claims 1, 3, and 5, specifying that the claimed compounds and compositions are of polymorph B only overcomes the art rejections made over Schnur ('498) in points #13-#16. Applicants state in lines 15-19, page 16 that the material of Schnur ('498) is a mixture of polymorphs A and B. Purer materials necessarily differ from impure materials. The motivation to prepare purer material for human use is obvious. However, preparing crystalline modifications and polymorphs is an unpredictable art. There is no objective evidence establishing that any method was known to those skilled in process chemistry field whereby the claimed pure polymorph might have been synthesized. Claim 64 is drawn to treatment of specific cancers by any polymorph of the claimed compounds. These specific cancers are not found in Schnur ('498). .

The Examiner appreciates Applicants' cooperation about the references of IDS #5.

TCMcK  
April 19, 2003



MUKUND J. SHAH  
SUPERVISORY PATENT EXAMINER  
GROUP 1600